

Claims

1. An assay device to determine the presence of at least one analyte of interest in a liquid sample, the device comprising means for generating a first signal, or "test" signal, which indicates the presence and/or amount of analyte of interest in the sample; and means for generating a second signal, the generation of which second signal indicates both
 - (a) the test has been successfully conducted, and that
 - (b) sufficient time has elapsed following contact of the assay device with the liquid sample for the test to be read and for the first signal to have been properly generated.
2. A device according to claim 1, wherein the analyte is hCG.
3. A lateral flow immunochromatographic assay device according to claim 1 or 2.
4. A device according to any one of claims 1, 2 or 3, wherein the means for generating the first signal, and the means for generating the second signal, comprise a latex-labelled specific binding reagent.
5. A device according to any one of the preceding claims, wherein the second signal is generated about 1 minute after the device is contacted with the sample.
6. A device according to any one of the preceding claims wherein the second signal is a visible signal which appears in a portion of the test device covered by a layer of translucent material.
7. A device according to any one of the preceding claims, wherein the second signal has a signal development time of less than 10 seconds.
8. A device according to claim 7, wherein the second signal has a signal development time of less than 8 seconds.

9. A device according to any one of the preceding claims, wherein the device comprises a depot of labelled, analyte-specific binding reagent and, downstream thereof, a depot of labelled, control specific binding reagent.
10. A method of performing an assay to determine the presence of an analyte of interest in a sample, the method comprising the steps of: contacting an assay device according to any one of claims 1-9 with the sample; observing the appearance of the second signal; and observing the appearance of the first signal when the second signal has appeared.
11. A method according to claim 10, wherein the sample is a sample of body fluid.
12. A method according to claim 11, wherein the sample is urine.
13. A method according to any one of claims 10, 11 or 12, wherein the analyte of interest is hCG.